This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

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April 19, 1999

Ms. Kathleen Meier
Chemical Review Manager – Oxydemeton-methyl
OPP/SRRD (7508W)
Environmental Protection Agency
401 M. St. SW
Washington, D.C. 20460
FAX (703) 308-8041

Re: Oxydemeton-methyl – chronic dietary endpoint
MRID 00039839

Dear Ms. Meier:

This letter is written in response to our telephone conversation of April 15, 1999, during which you indicated that EPA intends to change the critical study upon which to base the chronic dietary endpoint and reference dose for oxydemeton-methyl (ODM). Gowan Company is grateful for your informal efforts to keep us apprised of apparent new Agency policy; however we must request immediate and formal clarification of this, particularly in view of the relatively advanced stage of the reregistration of ODM.

As you are aware, the critical study used to set the chronic reference dose by EPA has been MRID 00039839, which is a cholinesterase inhibition study in human volunteers. Study MRID 00039839 was reviewed by EPA toxicologists on two occasions (Coberly, HED Doc# 000124 and more recently, Anderson, DP Barcode 235688, May, 1997). Both reviews classified the study as acceptable for a 1-day and 24 to 120 day human study for plasma and erythrocyte cholinesterase inhibition. Further, this study was subsequently chosen by the HAZID Endpoint Selection Committee on two occasions as the basis for the chronic dietary reference dose. The Committee's conclusions were released to Gowan Company on July 29, 1997 and July 24, 1998. The chronic endpoint was again reiterated in the draft Reregistration Eligibility Decision dated October 13, 1998.

We understand that EPA now proposes to utilize a one year dog study to set the chronic reference dose.

Gowan Company respectfully requests immediate and formal clarification, in writing, of the Agency's apparent intention to modify the findings of two separate scientific reviews, and the conclusions reached in the three Agency position statements made to date. Specifically, we wish to know:

1. Has another review been made of study MRID 00039839? If so, please explain the rationale for this in light of the fact that the previous reviews found the study to be acceptable. Also, if

another formal review has been made, we request that a copy of this is supplied to Gowan Company as soon as possible.

2. Are there other reasons or new formal policies not yet publicly available upon which the Agency will base rejection of scientifically valid human data in favor of animal data? If so, we request clarification of the Agency's rationale and copies of any new policies.

3. Is the Agency also intending to reject study MRID 00039839 from consideration in reregistration issues other than the setting of reference doses?

As a final note, we point out that for all other aspects of the reregistration process, the Agency has set schedules allowing for registrant comment on draft RED documents. We view changing of the chronic dietary endpoint to be a significant modification of the Agency's position, made at a very late date in the reregistration process. Once Gowan Company receives formal communication from the Agency regarding the proposed new chronic endpoint it is our view that the comment "clock" has restarted.

Thank you for your continued assistance with the reregistration of ODM. An electronic copy of this letter is being supplied; and we request that it be included in the public docket for ODM.

Sincerely,

Elizabeth Codrea
Regulatory Product Manager